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	29C0001045	A. BUILDING _____ B. WING _____	12/30/2009

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THE SURGICAL CENTER AT TENAYA	2650 TENAYA WAY LAS VEGAS, NV 89128

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Q 000	INITIAL COMMENTS Surveyor: 26907 This Statement of Deficiencies was generated as a result of the Medicare recertification survey conducted at your facility on December 29, 2009 through December 30, 2009 in accordance with 42 CFR 416, Requirements for Ambulatory Surgery Centers. An Immediate Jeopardy situation was identified on 12/29/09 at 3:00 PM, at CFR 416.51, Condition Level, Infection Control Program. The Immediate Jeopardy was abated at 3:00 PM on 12/30/09. Please refer to Tag Q240. The findings and conclusions of any investigation by the Health Division shall not be construed as prohibiting any criminal or civil investigation, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws. The following regulatory deficiencies were identified.	Q 000		
Q 240	416.51 INFECTION CONTROL The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases. This CONDITION is not met as evidenced by: Surveyor: 22489 Based on observation, interview, and record review, the facility failed to maintain an infection control program that prevents the potential spread of infections and communicable diseases due to the re-use and improper disinfection of dental syringes from patient to patient.	Q 240		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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Q 240	Continued From page 1 Findings include: On 12/29/09 in the morning, the surgery schedule listed 28 procedures to be completed for the day at the Ambulatory Surgical Center (ASC). All the procedures were to be performed on pediatric patients with ages ranging from 2 years old to 9 years old. Five cases were being performed by a Doctor of Dental Medicine (DMD) and twenty three procedures were being performed by a Doctor of Dental Surgery (DDS). On 12/29/09 in the morning, a dental restoration procedure was observed on a 5 year old female. The DMD was assisted by a dental assistant and a surgical technician. (Note: During the procedure, moderate amounts of blood was being suctioned from the patient's mouth. Several gauzes were used to wipe blood from the oral cavity. After the procedure, the gauzes had moderate amount of blood on them. Around the surgical field, on top of a tray, were surgical instruments and prefilled dental syringes used for the procedure.) When the procedure was completed, the instruments were separated and taken to the decontamination room for sterilization. The dental assistant took the used prefilled dental syringes that were just used on the case, and quickly swiped the syringes with a CaviWipes towelette. The dental assistant also replaced the used blunt needle tips with new ones. The dental assistant covered the surgical tray with a new clean blue cloth then proceeded to arrange the dental syringes on top of the tray. The dental assistant then placed another clean blue cloth over the tray covering the syringes.	Q 240		

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Q 240	Continued From page 2 Within 2 to 3 minutes a Surgical Technician #1 entered the room and took the blue cloth off the tray. The surgical technician was placing new instruments on the tray. The surveyor asked the surgical technician #1 if the syringes that were just cleaned and arranged on the tray were going to be used for the next case. The surgical technician #1 stated, "Yes." The surveyor brought attention to one of the dental syringes that was tinged with blood on the base of the barrel where the middle finger and the index finger would be placed to expel the contents of the syringe out. The base of the barrel also had a label taped at the base of the barrel which had tinges of blood on the label. The surveyor turned around immediately to inform the circulating nurse that the use of the blood tinged syringe was not acceptable to use on the next case. (Note: At that time, the surgical technician took the syringe out of the tray and indicated to the surveyor that the syringe would not be used.) On 12/29/09 in the morning, the Administrator indicated that used prefilled dental syringes were used for multiple patients. The syringes were not injected under the skin and the blunt needles did not puncture the skin, but the syringes with the blunt needle were placed in the oral cavity to inject the contents into the site. The cleaning procedure was to wipe down each syringe with a disinfectant (CaviWipes towelette) after each patient use and replace the blunt tip needle with a new one. When the surveyor asked if these products could be placed in a sterile container on the surgical field, the Administrator indicated some of the	Q 240		

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Q 240	Continued From page 3	Q 240		

prefilled products could not be injected on the surgical field before it was used because some products activated when it came into contact with air. Some products would become hard or contain air bubbles and then could not be used. The administrator indicated some of the products were very costly.

On 12/29/09 in the afternoon, the Administrator gathered all the brands of prefilled dental syringes used at the facility. The Administrator gave 3 types of prefilled syringes and the manufacturers instructions documented:

- "...Diapex... Premixed Calcium hydroxide paste containing Iodoform...."

- "...Lime-Lite.... Light cure, fluoride releasing, radiopaque cavity liner and base material specially formulated for use with adhesives, composites and conventional restorative materials...contains hydroxyapatite in a urethane dimethacrylate resin..."

- "...Etch Gel 40% is a water based 40% Phosphoric Acid Gel..."

The color of the Lime-Lite syringe and plunger was black making it difficult to assess if any blood or secretions were present (or removed with cleaning and disinfecting). The syringe and plunger would also be difficult to clean with a towelette due to the grooves and small corners of the barrel and the plunger not being in contact with the disinfecting solution.

On 12/30/09 in the afternoon, the infection control coordinator indicated she was not aware that the practice of re-using dental syringes from patient

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Q 240	Continued From page 4 to patient was being practiced at the facility prior to the surveyor's observation. After the surveyor explained to the infection control coordinator what the surveyor observed on 12/29/09, the infection control coordinator indicated that the practice was unacceptable. The infection control coordinator acknowledged the syringes should not be re-used due to syringes being handled by blood infected gloves during a procedure and the syringes would be placed in the oral cavity that may contain blood and open sores. The infection control coordinator indicated that the use of CaviWipes were not sufficient with cleaning and disinfecting the syringes due to the solution not coming into contact in small grooves of the syringe and the required soak time to decontaminate the syringe. On 12/29/09 in the afternoon, the surveyor attempted to contact the manufacturer's representative for the Diapex product. The surveyor asked the representative if their prefilled syringe product could be used from patient to patient in a ASC setting. The representative indicated there was no documented evidence she could find for reuse of the prefilled syringe from patient to patient in the setting described. The representative indicated she would not re-use the syringe from patient to patient. On 12/30/09 in the morning, the manufacturer's representative for the Lime-Lite product was contacted and asked if their prefilled syringes could be used from patient to patient in a ASC setting with moderate amounts of blood noted for each procedure. The representative could not answer the question and referred the surveyor to a representative from the legal department. Surveyor: 27178	Q 240		

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Q 240	Continued From page 5 On 12/29/09 at 2:40 PM, during a conference meeting with the ASC's Administrator, Operating Room Manager, DMD and Surgical Technician #2, the Surgical Technician #2 indicated the Etch Gel was supplied in a 60 cubic centimeter (cc) syringe along with 5 empty 3 cc syringes in a kit. The Surgical Technician #2 indicated the 3 cc syringes were intended for multiple patient use as supplied by the manufacturer. The Surgical Technician #2 indicated, each 3 cc syringe was cleaned by the use of CaviWipes after each patient use. Once cleaned, the syringes were reattached via a luer lock connection to the 60 cc syringe containing Etch Gel for refill, to be used for the next dental procedure. A surveyor brought up the concern regarding the syringes being used for different cases and/or patients. The Surgical Technician #2 indicated the applicator tips were the ones that touched the patients' mouth and they were being changed after each patient use. On 12/29/09 in the afternoon, during the conference, the DMD added this has been a common dental practice within the community. The DMD indicated the syringes for the Etch Gel were not the only ones being re-used, but also the pre-filled Revolution syringes as well, due to its high cost. On 12/30/09 at 3:30 PM, interview with the ASC's Infection Control Nurse revealed she was not	Q 240		

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Q 240	Continued From page 6 aware of this practice until 12/29/09, in the afternoon, when these concerns were brought to her attention by the ASC's administrator. The Infection Control Nurse further revealed, "The syringes should have been discarded after each patient use. If the syringes were already used for a patient, then, the syringes should not be re-used for another patient." Surveyor: 26907 Post-Survey Research: On 1/5/2010 at 3:00 PM, the surveyor spoke with a customer service representative of Metrex Corporation, manufacturer of CaviWipes products regarding the correct usage of CaviWipes. The representative indicated the CaviWipes must be used according to manufacturer's guidelines. This included keeping the device to be disinfected saturated for at least 2 - 3 minutes in order to kill the various organisms, as indicated in the CaviWipes brochure. The representative added the CaviWipes should not be used on syringes, adding the syringe should be sterilized. The representative also indicated the CaviWipes should not be used on devices that were contaminated with blood. The manufacturer's guidelines indicated the CaviWipes are recommended for use on: "Infant incubators, cribs, and warmers; Anesthesia machines and respiratory therapy equipment; Laboratory equipment; Ambulance equipment; Tables, chairs and workstations;	Q 240		

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Q 240	Continued From page 7 IV poles, bed railings and handrails; Telephones; Bathroom fixtures." Product Use: "CaviWipes is used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high level disinfection. Use one CaviWipes towelette to completely preclean surfaces of all gross debris. To disinfect the precleaned surface, use a second CaviWipes towelette to thoroughly wet the surface and allow to remain visibly wet for 3 minutes. For tuberculocidal disinfection, allow the surface to remain wet for 3 minutes." On 1/8/2010 at 11:45 AM, the surveyor talked with a Technical Support Staff from Metrex regarding the proper use of CaviWipes. The Tech Support staff indicated Cavicide and CaviWipes are meant to be used on hard surfaces, not on porous surfaces. Anything going into a body cavity would not be appropriate to disinfect with CaviWipes. When asked by the surveyor if CaviWipes could be used on a syringe, the Tech support staff indicated it would not be appropriate. He added the syringe should be sterilized or discarded. There was no documented evidence CaviWipes were recommended for use on syringes. On 1/8/10 at 10:45 AM, the surveyor spoke with a Purchasing Representative at Diapex regarding the proper use of the product. When asked by the surveyor if the product is intended for use on multiple patients, he indicated that is was not meant for multiple patient use.	Q 240		

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The surveyor then spoke with the Marketing Manager for Diapex. She indicated she believed it could be used for multiple patients. When asked what the recommendations were regarding cleaning the product between patients, she indicated she had no knowledge regarding that aspect and would call the manufacturer in Korea.

On 1/8/10 in the morning, the surveyor spoke with a Manufacturer's Representative with Pulp Dent Corporation regarding the proper use of the Lime-Lite product. The representative indicated that Lime-Lite can be used on multiple patients by changing the tip. He also indicated, if the syringe was used on multiple patients, a sleeve could be used to cover the syringe. If no sleeve was used, the syringe should be sterilized between patients or discarded if the syringe was plastic.

The Representative also indicated the Lime-Light Product can be dispensed into a Sterile cup on the surgical field and then applied. This would prevent the reuse of syringes that have entered a patient's oral cavity.

The Representative added, the company does not supply the plastic sleeve to cover the syringe or include explicit directions in the manufacturer's guidelines as to proper cleaning techniques, since it was "common knowledge" by the dentists as to the proper procedures.

The Representative also indicated the Lime-Lite product was available in individual doses, but the cost would be three times the price of the multi-dose syringe.

On 1/8/2010 at 2:30 PM, the surveyor spoke with

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Q 240	Continued From page 9 a Customer Service Representative with Septadent Dental Products, Manufacturer of Etch Gel Products. The representative indicated the syringes should not be used on multiple patients. There were 2 methods to use the product. The first would be to apply the product using the brush tip, and then dispose of the product. The second method would be to squirt the material into a dish located on the surgical table and then use the product from the dish. The Representative indicated the 3 cc (cubic centimeter) syringe should never be used on multiple patients.	Q 240		
Q 241	416.51(a) SANITARY ENVIRONMENT The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. This STANDARD is not met as evidenced by: Surveyor: 22489 Based on observation, interview, and record review, the facility failed to follow acceptable standards to provide a sanitary environment. Findings include: 1. On 12/30/09 in the afternoon, the preoperative/post anesthesia care unit (PACU) nurse manager indicated the blood glucose machine was used from patient to patient. The manager indicated the machine was cleaned with alcohol only when it was visibly soiled. On 12/30/09 in the afternoon, the infection control coordinator indicated the facility policy for cleaning the glucose monitor was to clean the	Q 241		

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Q 241	Continued From page 10 machine before and after use with a patient. 2. On 12/29/09 in the morning, the surgical technician indicated laryngeal mask airways (LMA) were re-used and sterilized after each patient use. The surgical technician indicated that he was aware the manufacturer recommended that the LMA's be sterilized a maximum of 40 times. The surgical technician indicated that there was no tracking system the facility followed to determine how many times an LMA was used. 3. On 12/29/09 in the morning, a dental procedure was observed. The surgical technician #1 was opening the trash bin by lifting the lid with her non gloved hands. The technician did not use the foot pedal to open the trash bin. The surgical technician did not wash her hands. She then donned clean gloves and assisted the dental assistant and the Doctor of Dental Medicine (DMD) with the procedure. 4. On 12/30/09 in the morning, all the used prefilled dental syringes were collected and placed in a clear plastic bag. On 12/30/09 in the morning, shelves located in the operating room hallway area contained clear and brown covered containers labeled with physician names. The surgical technician indicated the containers were used by physicians to store their supplies used for procedures. The surgical technician indicated the containers were never checked by staff members and he was not aware what specific items were kept in the containers. New prefilled 1.7 ml (milliliter) 2% Lidocaine cartridges were found in some containers. Also	Q 241		

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Q 241	Continued From page 11 found in a container were seven used prefilled black colored dental syringes that had blunt needles connected to the syringe and labeled Filtek supreme plus. New prefilled syringes were mixed with the used ones. 5. On 12/29/09 in the morning, after procedures were completed instruments were being transported from the operating rooms to the decontamination room in a containers that were not covered. On 12/30/09 in the morning, the nurse manager for surgical services confirmed that the staff members needed to cover dirty instruments while transporting them out of the operating rooms and the standards followed by the facility was Association of periOperative Registered Nurses (AORN). AORN standards and recommended practices 2009 edition page 581 documented: -"...Soiled instruments and devices should be handled using PPE (personal protective equipment) and transported in a contained, covered, and secure manner to the point of decontamination and processing..." On 12/30/09 in the morning, the decontamination room had a large window that separated the decontamination from the sterilization room. The window was kept open throughout the 2 day survey and when instruments were being decontaminated.	Q 241		
Q 245	416.51(b)(3) INFECTION CONTROL PROGRAM - RESPONSIBITIES The program is -	Q 245		

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Q 245	Continued From page 12 Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement. This STANDARD is not met as evidenced by: Surveyor: 27178 Based on record review and interview, the ASC failed to comply with the physical examination requirements for its employees for infection control prevention, identification and management. Findings include: On 12/29/09 in the afternoon, eight personnel files were reviewed. All eight files lacked documented evidence that the employees received physical examination or certification from a licensed physician that the employees were in a state of good health and were free from any communicable disease. On 12/29/09 at 4:55 PM, interview with the ASC's Administrator revealed, the ASC did not require pre-employment physicals from their employees.	Q 245		